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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,945	05/02/2001	Neil P. Desai	ABI1460-3 (071243-1317)	6174

7590 11/22/2002

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EXAMINER
DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 11/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/847,945	DESAI ET AL	
	Examiner	Art Unit	
	Robert M DeWitty	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-30 are pending in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 18, 20-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Shashoua et al. (U.S. Pat. No. 5,795,909).

Shashoua teaches taxanes useful in treating cell proliferative disorders. Conjugates of paclitaxel and docetaxel are preferred. The products of the invention are also useful in treating conditions specific to noncentral nervous system tissue, such as tissue of the blood vessel wall (col. 6, lines 11-19). Pharmaceutical agents may be conjugated to the drug compound (col. 19, lines 62-67), such as anti-dorsalizing morphogenetic protein-1 (col. 31, lines 47-48), single chain antigen binding protein (col. 33, line 12), and somatomedin binding protein (col. 33, line 14). Modes of administration include oral, transdermal, or parenteral routes (col. 49, lines 28-30). Thus, the above claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-8, 17-24, and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shashoua et al. (U.S. Pat. No. 5,795,909).

As stated above, Shashoua teaches taxanes,s uch as paclitaxel and docetaxel, useful in treating cell proliferative disorders. As shown in the prior art, Taxol is known to bind to proteins (col. 3, line 10). The products of the invention are also useful in treating conditions specific to noncentral nervous system tissue, such as tissue of the blood vessel wall (col. 6, lines 11-19). Pharmaceutical agents may be conjugated to the drug compound (col. 19, lines 62-67), such as anti-dorsalizing morphogenetic protein-1 (col. 31, lines 47-48), single chain antigen binding protein (col. 33, line 12), and somatomedin binding protein (col. 33, line 14). The compounds may be delivered in the form of anti-cancer cocktails: a common administration vehicle (pill, tablet, or implant) (col. 47, lines 41-51) can be used. Daily oral doses of active compounds will be from about 0.01mg/kg per day to 1000 mg/kg per day (col. 49, line 9-11). Modes of administration include oral, transdermal, or parenteral routes (col. 49, lines 28-30).

In view of the teachings of Shashoua, it is the examiner's position that a method for treating hyperplasia using a drug and protein would have been obvious to one with

ordinary skill in the art. Whereas Shashoua does not explicitly disclose that hyperplasia may be treated, the patent does disclose that the invention is useful in treating cell proliferative disorders. As hyperplasia is defined as "the abnormal multiplication or increase in the number of normal cells in normal arrangement in a tissue" (Dorland's Dictionary, page 798), it is believed that Shashoua's treatment covers hyperplasia.

In preparation of the compositions, finely divided solid carrier particles were used to shape the product (col. 49, lines 39-41). As taught by Shashoua, the physical condition, size and weight of the composition is a factor that is well-known to those with ordinary skill in the art and can be addressed with no more than routine experimentation (col. 49, line 5-8). It is the examiner's position that modification of the product in terms of its size and form would have been performed to achieve optimization.

Thus, the invention is made obvious.

3. Claims 9-16 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shashoua et al. (U.S. Pat. No. 5,795,909), further in view of Li et al. (U.S. Pat. No. 5,977,163).

In addition to the teachings above, Shashoua et al. teaches that a long-term sustained release implant also may be used (col. 50, lines 10-11). Long term release means that the implant is constructed and arranged to deliver therapeutic levels of active ingredient (col. 50, lines 11-13). However, Shashoua does not teach what type of implant is used, such as a stent.

Li et al. relates to pharmaceutical compositions to be used in the treatment of cancer and restenosis. The benefits of the compositions are that the formulations have

long serum half lives for treatment of tumors, as well as for the prevention of restenosis of vessels subject to traumas such as angioplasty and stenting (col. 2, lines 30-36). Li et al. states that it has been found that paclitaxel inhibits restenosis after balloon angioplasty (col. 5, lines 66-67). It is contemplated that water soluble paclitaxel will be useful as a coating for implanted medical devices, such as balloon-expandable stents (col. 6, lines 4-8).

One with ordinary skill in the art would have been motivated to utilize the stent of Li et al., comprising a paclitaxel-formulation coated-stent, in the invention of Shashoua in order to inhibit restenosis after balloon angioplasty.

Thus, the invention is made obvious.

Response to Arguments

4. Applicant's arguments with respect to claims 1-30 have been considered and the previous rejection under 35 U.S.C. 103(a) (Hunter et al.) has been withdrawn based on the arguments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
November 17, 2002

JOSE' G. DIEZ
SUPERVISORY PATENT EXAMINER
1616